

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

# PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:  
STEPHEN B. SHEAR  
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Date of mailing  
(day/month/year) **06 OCT 2005**  
**FOR FURTHER ACTION**  
See paragraph 2 below

Applicant's or agent's file reference 53000 PCT		
International application No. PCT/US05/05695	International filing date (day/month/year) 23 February 2005 (23.02.2005)	Priority date (day/month/year) 26 February 2004 (26.02.2004)
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61F 6/02, 6/04, 5/451, 5/453; B32B 1/08; F16L 11/04 and US Cl.: 128/844, 842, 918; 604/347-354; 428/34.1, 36.9; 138/118.1		
Applicant CHURCH & DWIGHT CO. INC.		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I      Basis of the opinion
- ☐ Box No. II      Priority
- ☐ Box No. III      Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV      Lack of unity of invention
- ☒ Box No. V      Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI      Certain documents cited
- ☐ Box No. VII      Certain defects in the international application
- ☐ Box No. VIII      Certain observations on the international application

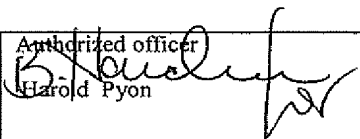
## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Date of completion of this opinion 12 September 2005 (12.09.2005)	Authorized officer  Harold Pyon Telephone No. 571-272-1700
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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US05/05695

**Box No. I Basis of this opinion**

1. With regard to the **language**, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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International application No.  
PCT/US05/05695

**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims <u>1-9</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-9</u>	NO
Industrial applicability (IA)	Claims <u>1-9</u>	YES
	Claims <u>NONE</u>	NO

**2. Citations and explanations:**

Claims 1-9 lack an inventive step under PCT Article 33(3) as being obvious over Harrison et al in view of Ahmad et al.

Harrison et al teach a packaged condom comprising a male genital engaging tubular sheath having an inner surface and an outer surface together with a lubricating composition comprising one or more glycols located on both the inner and outside surface of the sheath (see abstract and Figure 1). The lubricating composition comprises propylene glycol, polyethylene glycol, and Lubrajel, which comprises glyceryl polymethacrylate (p.2, paragraph 21). Harrison et al gives examples of the amount of each component of the composition, but it would be obvious to one having ordinary skill in the art to optimize the amount of propylene glycol, polyethylene glycol and Lubrajel in the lubricant composition depending on the intended end result of the lubricant. Also, it would have been obvious to one having ordinary skill in the art to apply the claimed amount of the lubricating composition in the inner and exterior surfaces of the condom depending on the size and shape of the condom the lubricant is applied to and the desired thickness of the lubricant on the condom.

Harrison et al fail to explicitly teach that the lubricating composition warms upon contact with compositions containing free water or that glycerin is added to the lubricating composition. However, Ahmad et al teach that when lubricating compositions containing polyhydric alcohols such as propylene glycol and polyethylene glycol are used containing little water, come in contact with free water or body moisture in humans, they react with the ambient water molecules to cause an increase in temperature or generate warmth, thus having a soothing effect on the tissues to which these compositions are in contact (p.3, paragraph 26). Ahmad et al also teach that glycerin is a well-known polyhydric alcohol that is also mixed with propylene and ethylene glycols when forming lubricants for condoms.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form the lubricant composition of Harrison et al with a low concentration of water so that the lubricant on contact with free water in the form of body moisture would react with the ambient water molecules causing an increase in temperature or warmth generation, that soothes the tissues the lubricant comes in contact with and thus eliminates the feeling or perception of cold that conventional personal lubricants convey upon use, as taught by Ahmad et al.

Claims 1-9 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Claims 1-9 have industrial applicability because the packaged condom can be used in the contraceptive industry.